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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,556	02/04/2000	George Phillip Vlasuk	250/191	8959

7590 05/06/2003

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EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/06/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/498,556

Applicant(s)

VLASUK ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 270-282 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 270-282 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

Status of the claims

A preliminary amendment (paper #2, filed on February 4, 2000) and a supplemental preliminary amendment (paper #6, filed on January 10, 2001) is acknowledged. Claims 1-269 have been canceled and new claims 270-282 have been added. Therefore, claims 270-282 are currently pending and are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 270-281 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 270 (e, j), 271 (h, j), 272 and 273 reciting "SEQ. ID. NO.", "SEQ ID NO:" should be used.

Claims 270, 271, 272, and dependent claims thereto are indefinite because of the use of the term "NAP." The term "NAP" renders the claim indefinite, it is unclear what "NAP" is. The full spelled out words should precede an acronym/abbreviation unless "NAP" is meant to be Asn-Ala-Pro.

Claims 270-274, and dependent claims thereto are indefinite because of the use of the term "AcaNAPc2." The term "AcaNAPc2" renders the claim indefinite, it is unclear what "AcaNAPc2" is. The full spelled out words should precede an acronym/abbreviation.

In claims 270 and 271 (item j, second to last line) and in claims 272, 273 and 274, it is not clear what is or is not the "amino acid sequences substantially the same as..." with regard to retention of NAP domain function.

Claims 270 and 271 are indefinite because of the use of the phrase "less than about 120 amino acid residues." This phrase renders the claim indefinite, it is unclear what is the upper limit for the amino acid residues in the NAP domain, as "about" would also read on less than 120.

Claims 275-281 are indefinite because they lack essential steps as claimed in the process of treating a pathologic condition by administering a protein of claims 270-274. The omitted steps are: the site and method of administration, the therapeutically effective amount of the agent and a step whereby the desired outcome and the time for the effective treatment using the said protein can be determined.

Claim Rejections - Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 270, 271, 275 and 282 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 30 and 33 of U.S. Patent No. 5,872,098. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 270 and 271 are directed to the broadest scope of the protein having anticoagulant activity and having one or more NAP domains. Claim 270 and 271 encompass the amino acid sequences set forth in claim 1 of patent '098.

Claim 270 (c) discloses an amino acid sequence A3 having 3 amino acid residues Asp-A3a-A3b. This is an obvious variation of claim 1(c) in the patent '098, which discloses an amino acid sequence A3 having any 3 amino acid residues.

Claim 270 (d) discloses an amino acid sequence A4 having a net anionic charge. This is an obvious variation of claim 1(d) in the patent '098, which discloses an amino acid sequence A4 having any charge.

Claim 270 (e) discloses an amino acid sequence A5 having 4 amino acid residues A5a-A5b-A5c-A5d (SEQ ID NO: 59). This is an obvious variation of claim 1(e) in the patent '098, which discloses an amino acid sequence A5 having 3-4 amino acid residues.

Claim 270 (g) discloses an amino acid sequence A7, residues selected from the group consisting of val and Ile. This is an obvious variation of claim 1(g) in the patent '098, which discloses an amino acid sequence A7 having any amino acid residues.

Claim 270 (j) discloses an amino acid sequence A10 having a NAP domain same as the NAP domain of AcaNAPc2 (SEQ ID NO: 59). This is an obvious variation of claim 1(j) in the patent '098 which discloses an amino acid sequence A10, wherein the protein is derived from a hematophagous nematode species.

Claim 271 (c) discloses an amino acid sequence A3 having 3 amino acid residues Asp-Lys-Lys. This is an obvious variation of claim 1(c) in the patent '098, which discloses an amino acid sequence A3 having any 3 amino acid residues.

Claim 271 (d) discloses an amino acid sequence A4 having a net anionic charge. This is an obvious variation of claim 1(d) in the patent '098, which discloses an amino acid sequence A4 having any charge.

Claim 271 (e) discloses an amino acid sequence A5 having 4 amino acid residues Leu-A5b-Arg-A5d (SEQ ID NO: 357). This is an obvious variation of claim 1(e) in the patent '098, which discloses an amino acid sequence A5 having 3-4 amino acid residues.

Claim 271 (g) discloses an amino acid sequence A7, which is Val. This is an obvious variation of claim 1(g) in the patent '098, which discloses an amino acid sequence A7 having any amino acid residues.

Claim 271 (h) discloses an amino acid sequence A8 having 11-12 amino acid residues A8a-A8b-Gly-Phe-Tyr-Arg-Asn (SEQ ID NO: 79), wherein at least one of A8a and A8b is Glu or Asp. This is an obvious variation of claim 1(h) in the patent '098, which discloses an amino acid sequence A8 having any 11-12 amino acid residues.

Claim 271 (j) discloses an amino acid sequence A10 having a NAP domain same as the NAP domain of AcaNAPc2 (SEQ ID NO: 59). This is an obvious variation of claim 1(j) in the patent '098 which discloses an amino acid sequence A10, wherein the protein is derived from a hematophagous nematode species.

Claim 275 discloses a method of treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 270. This is an obvious variation of claim 33 in the patent '098, which discloses a method of inhibiting blood coagulation by administering a protein of claim 1.

Claim 282 discloses a pharmaceutical composition comprising a protein of claim 270-274. This is an obvious variation of claim 30 in the patent '098, which discloses a pharmaceutical composition comprising a protein of claim 1.

Thus, claims 270, 271, 275 and 282 in present application and claims 1, 30 and 33 in the patent '098 are obvious variations of an isolated protein having an anticoagulant activity and NAP domains, wherein each NAP domain includes the sequence:

Cys-A1-Cys-A2-Cys-A3-Cys-A4- Cys-A5-Cys-A6- Cys-A7-Cys-A8-Cys-A9-Cys-A10
(formula III).

Claims 272-280 and 282 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 35, 36, 37, 39, 41, 43, 47, 49, 38, 40, 42, 44, 48, 50, 22-25 of U.S. Patent No. 5,866,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 272 is directed to the broadest scope of the protein having Factor VIIa/TF inhibitory activity and having a NAP domain with an amino acid sequence substantially the same as the NAP domain of AcaNAPc2 (SEQ ID NO: 59). Claim 272 is encompassed by the amino acid sequences set forth in claim 21 of Patent '542. This is an obvious variation of claim 21 in the patent '542, which discloses a protein having a NAP domain with an amino acid sequence of AcaNAPc2 (SEQ ID NO: 59).

Claim 273 discloses a protein having an amino acid sequence substantially the same as AcaNAPc2 (SEQ ID NO: 59). Claim 273 is encompassed by the amino acid sequences set forth in claim 35 of Patent '542. This is an obvious variation of claim 35 in the patent '542, which discloses a protein having an amino acid sequence of AcaNAPc2 (SEQ ID NO: 59).

Claim 274 discloses a protein having an amino acid sequence substantially the same as AcaNAPc2/proline. Claim 274 is encompassed by the amino acid sequences set forth in claim 36 of Patent '542. This is an obvious variation of claim 36 in the patent '542, which discloses a protein having an amino acid sequence of AcaNAPc2/proline.

Claim 275 discloses a method of treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 270. This is an obvious variation of claims 37 and 39 in the patent '542 which disclose treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 1 and 15 respectively.

Claim 276 discloses a method of treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 271. This is an obvious variation of claim 41 in the patent '542, which discloses

treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 18.

Claim 277 discloses a method of treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 272. This is an obvious variation of claim 43 in the patent '542, which discloses treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 21.

Claim 278 discloses a method of treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 273. This is an obvious variation of claim 47 in the patent '542, which discloses treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 35.

Claim 279 discloses a method of treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 274. This is an obvious variation of claim 49 in the patent '542, which discloses treating a pathologic condition characterized by abnormal thrombosis by preventing or decreasing the abnormal thrombosis by administering a protein of claim 36.

Claim 280 discloses a method of treating a pathologic condition characterized by disseminated intravascular coagulopathy by administering a protein of claim 270-274 of methods of claims 275-279. This is an obvious variation of claims 38, 40, 42, 44, 48 and 50 in the patent '542 which discloses treating a pathologic condition characterized by disseminated intravascular coagulopathy by administering a protein of claims 37, 39, 41, 43, 47 and 49.

Claim 282 discloses a pharmaceutical composition comprising a protein of claim 270-274. This is an obvious variation of claims 22-25 in the patent '542, which discloses a

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pharmaceutical composition comprising a protein of claim 1, 15, 18 and an AcaNAPc2 protein (SEQ ID NO: 59) respectively.

Thus, claims 272-280 and 282 in present application and claims 21-25, 35-44, 47-50 in the patent '542 are obvious variations of an isolated protein having Factor VIIa/TF inhibitory activity and having a NAP domain with an amino acid sequence substantially the same as the NAP domain of AcaNAPc2 (SEQ ID NO: 59).

Claims 270 and 272 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 of U.S. Patent No 6,090,916. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 272 is directed to the broadest scope of the protein having Factor VIIa/TF inhibitory activity and having a NAP domain with an amino acid sequence substantially the same as the NAP domain of AcaNAPc2 (SEQ ID NO: 59). Claim 272 and 270 are encompassed by the amino acid sequences set forth in claim 2 of patent '916. This is obvious in view of claim 2 in the patent '916 which discloses a protein having anticoagulant activity, and having one or more NAP domains, wherein each NAP domain includes the sequence of Formula III with difference in the values of A3, A4, A5, A7, A8 and A10 of items c, d, e, g, h and j (see above analysis of patent '098).

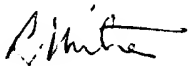
Thus, claims 270 and 272 in present application and claim 2 in the patent '916 are obvious variations of an isolated protein having Factor VIIa/TF inhibitory activity and having a NAP domain with an amino acid sequence substantially the same as the NAP domain of AcaNAPc2 (SEQ ID NO: 59).

Conclusion

No claims are allowed.

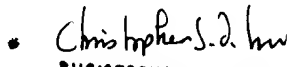
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

May 3, 2003


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